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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,885	09/30/2005	Yasuo Omi	1141/75103	6799

23432 7590 06/21/2010

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EXAMINER	
GUPTA, VANI	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
06/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,885	OMI ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-19,21 and 22* is/are rejected.

7)☒ Claim(s) *1,11 and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2010 has been entered.

Claim Objections

1. ***Claim 1 is objected to because of the following informalities:***

- Line 1 is missing a colon (":") after "comprising".
- Line 2 includes a comma after "examined". It should be replaced with a semi-colon (";")
- Lines 3, 5, and 6: see comment for line 2.
- Line 8 includes a semi-colon (";") after "images." It should be replaced with a colon (":").
- Line 9: see comment for line 2.
- Lines 9 and 10 should include one more paragraph indentation to indicate that they are part of a list (or are a sub-step) from lines 7 - 8, and also to separate them from the remaining lines.
- Line 13: see comment for line 2.

2. ***Claim 11 is objected to because of the following informalities:***

- Line 1 is missing a colon (":") after "comprising".
- Line 2 includes a comma after "examined". It should be replaced with a semi-colon (";")
- Line 3, 6, and 7: see comment for line 2.
- Line 10 includes a semi-colon (";") after "images." It should be replaced with a colon (":").
- Line 9: see comment for line 2.
- Lines 9 and 10 should include one more paragraph indentation to indicate that they are part of a list (or are a sub-step) from lines 7 - 8, and also to separate them from the remaining lines.
- Line 13 is missing a semi-colon (";") after "image".

3. ***Claim 21 is objected to because of the following informalities:***

- Line 1 is missing a colon (":") after "comprising".
- Line 2 includes a comma after "examined". It should be replaced with a semi-colon (";").
- Lines 5, 12, 15, 18: see comment for line 2.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. ***Claims 14 and 15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.***

Claims 14 and 15 each include the phrase "is capable of," which is awkward and misplaced within the context of a method claim that generally should step(s) within a method. Rather this claim seems to read on functional feature of the display. Hence, these claims merely recite a use of the displaying an item without any active, positive steps delimiting how this use is actually practiced.

Please see rejections of these claims under 35 USC § 112, second paragraph, for further details.

See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. ***Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.***

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In line 6 of Claim 1, included is the feature "means for" forming or creating at least one functional image based on biological function data. However, the specification does not provide enough description of what this means is, nor does it provide details about how the creation of functional images is accomplished. While the specification expresses the use of "mapping," or a "program for mapping" in paragraphs [0046] and [0053], for example, it is not within the ordinary skill in the art because the specification is not clear about what the biological function data is being mapped onto, and/or how it is being mapped. Additionally, it is not clear whether the biological function data is possibly being mapped onto the previous acquired tomograms because it seems that Claim 1 later expresses an additional, separate, means for accomplishing this task in lines 7 – 11 ("means for forming a composite image by composing said tomogram..."). (This is also argued by Applicant as such on page 11, line 5…"created function image is synthesized with a tomogram."

6. ***Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.***

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, because it is not very clear what is being accomplished by the following:

"means for forming a composite image by composing said tomogram and at least one of the following images;

an operated image obtained by operating said functional images together,

a composite image obtained by composing said functional images together, said operated image, and said functional image."

Is the Applicant trying to claim means for forming to different types of composite image, or is the Applicant trying to claim forming one type of composite that may comprise 1) operated images or 2) and additional composite image that further comprises several functional images, an operated image, and another functional image?

Applicant is requested to either clarify this portion of Claim 1 by amendments or cancel Claim 1 altogether.

7. *Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*

Regarding Claim 8, Applicant claims that "the functional image forming part renders the pixel values of the pixels of the image data on a predetermined window level and in a predetermined window width to be corresponded to conversion coefficients, and determines said gradation color scale based on the conversion coefficients." However, neither this claim nor the disclosure is very clear on what this "window level" is. It seems that both the claim and the disclosure is a literal translation into English from a foreign document.

It is not clear whether window level refers to brightness, color versus gray-scale, image-size, centered or left/right justification, color intensity, etc. The specification and claims also are not very clear on what exactly what "conversion coefficients" are and how they relate to the

predetermined window level. It also not clear how either of these aspects of functional image data relate to a "predetermined window width," especially since the neither the claims nor the specification discuss a window *length*.

Applicant is requested to cancel this claim or amend it to clarify the meaning of window level – without introducing new matter – to overcome this rejection.

Claim 9 recites the limitation "the conversion coefficient" in line 4. There is insufficient antecedent basis for this limitation in the claim, since its parent claim (Claim 21) does not mention a conversion coefficient.

8. ***Claims 14 and 15 provides for the use of the apparatus as claimed in claim 1 or 21, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.***

In this instance, the each of the claims is stated to include a step of forming said functional image *capable* of arbitrarily setting [something]. For example, Claim 14 states "a method of displaying [an] image, wherein the step of forming said functional image *is capable of* arbitrarily varying the gradation color…" The phrase "is capable of" is awkward and misplaced within the context of a method claim that generally should step(s) within a method. Rather this claim seems to read on functional feature of the display. Claim 15 has similar problems. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Applicant is requested to cancel this claim or amend it to clarify the meaning of window level – without introducing new matter – to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. ***Claims 1 – 7, 10, 11, 13 – 15, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Nevo (US 6,224,553 B1).***

Regarding claims 1 and 11, Nevo describes an apparatus for displaying image comprising:

a. means for collecting image data of a person being examined *("raw image data," col. 5, ll. 26 – 29)*;

b. means for forming a tomogram from said image data *("variance image," col. 5, ll. 47 – 49)*; and

c. means for calculating at least one biological function data in said tomogram regarding temporal changes in values of the same pixels or section of an organ with passage of time *(col. 4, ll. 27 – 43; col. 8, line 16 – col. 9, line 15)*;

In light of the 35 U.S.C. 112 first paragraph rejection above, and for purposes of examination, Examiner looks to the present disclosure for meaning of functional images. Based on description in paragraph [0002] of the specification of the present application, Nevo provides means for forming at least one functional image based on said biological function data *(col. 4, ll. 44 – 63; col. 8, line 55 – col. 9, line 15)*, in that Nevo obtains images that portray functional

information such as "blood pools in the heart," and related blood flow information that is also depicted by the aforementioned tomogram.

In light of the 35 U.S.C. 112 second paragraph rejection above, and for purposes of examination, Examiner interprets "means for forming a composite image by composing said tomogram and at least one of the following images: an operated image obtained by operating said functional images together, a composite image obtained by composing said functional images together, said operated image, and said functional image;" to mean providing "means for" forming a tomogram (in addition to the one obtained above) by operating (averaging, subtracting, etc.) or composing (overlaying or overlapping) several functional images together. Nevo expresses providing capabilities to overlap several different types of images *(col. 4, ll. 53 - 54; col. 6, line 21 – col. 7, line 56; col. 9, ll. 34 – 35)*.

Nevo also discloses display means capable of displaying said functional image, said operated image, said tomogram and said composite image ***(fig. 1, #26)***, wherein the means for forming said functional image and the means for forming the composite image work to display at least portions of the regions in said functional image and in said operated image on an arbitrary gradation color scale corresponding to the evaluated value of said biological function data, and other regions in said function image and in said operated image are displayed in an arbitrary color which is not included in said gradation color scale, or are displayed transparently, and said portions of the regions in the functional image are displayed by an overlapped display *(col. 4, ll. 44 – 63; col. 5, ll. 54 - 67)*.

Regarding Claim 21, Nevo describes a functional image display apparatus comprising:

a. an acquisition part configured to collect image data of a person being examined *(see claim 1(a))*,

b. a tomogram forming part configured to form a tomogram from the image data *(see claim 1(b))*;

c. analysis part configured to calculate at least one biological function data in said tomogram regarding temporal changes in values of the same pixels or section of an organ with passage of time *(see Claim 1(c))*;

d. a functional image forming part configured to form at least one functional image based on the biological function data *(see Claim 1 about functional image data)*;

e. a composite image forming part configured to form a composite image by composing the tomogram and at least one of the functional image, an operated image obtained by performing an inter-image operation ("subtraction," and/or "averaging") on a plurality of functional images, and a blended image obtained by composing the functional images together *(see Claim 1 about composite images formed by operated images and/or additional composite images)*; and

f. a display part configured to display the functional image, the operated image, the tomogram and the composite image (see Claim 1 about display means), wherein at least portions of regions in the functional image and in the operated image are displayed on an arbitrary gradation color scale corresponding to the evaluated value of the biological function data, wherein other regions in the functional image and in the operated image are displayed in an arbitrary color which is not included in the gradation color scale, or

are displayed transparently, and wherein the portions of the regions in the functional image are displayed by an overlapped display *(see Claim 1 for this portion, as well)*.

Regarding Claim 2, Nevo disclose an apparatus according to claim 21, wherein said display is capable of displaying a composite image by either a parallel display or a partial display *(col. 7, ll. 38 – 42 and 46 – 48)*.

Regarding claims 3 and 13, Nevo disclose an apparatus according to claim 21, wherein said functional image forming part is capable of setting to zero a ratio of said functional image in other regions in said functional image *(col. 6, ll. 1 – 10)*.

Regarding claims 4 and 14, Nevo disclose an apparatus according to claim 21wherein said functional image forming part is capable of arbitrarily varying the gradation color scale allocated to said biological function data *(col. 5, ll. 54 – 67)*.

Regarding claims 5 and 15, Nevo disclose an apparatus according to claim 21, wherein said functional image forming part arbitrarily set ratios of the functional images in said composite images and of said tomogram *(col. 6, ll. 1 – 10)*.

Regarding claims 6 and 16, Nevo disclose an apparatus according to claim 21, wherein said functional image forming part is capable of specifying part of the regions in said functional image depending upon whether the image data value of said pixel unit lies inside or outside a predetermined range *(col. 6, line 21 – col. 7, line 56)*.

Regarding claims 7 and 17, Nevo disclose an apparatus according to claim 21, wherein said functional image forming part is capable of determines an arbitrary interested region in said functional image as region of interest in said functional image (*col. 8, line 55 – col. 9, line 15*.

Regarding claims 8 and 18, in light of the 35 U.S.C. 112 second paragraph rejection above, and for purposes of examination, Examiner interprets "window level" in Claim 8 to refer to the variances in the object being displayed - e.g. inhomogeneity of tissue – and how these differences are displayed, such as in a contour map. Nevo discusses using color-coded schemes, which may read as coefficients that can "covert" or change the colors of the different levels of variability or .

Nevo suggests the apparatus according to claim 21, wherein said functional image forming part renders the pixel values of the pixels of the image data on a predetermined window level and in a predetermined window width—which is based on the size of region of interest – to correspond to conversion coefficients, and determines said gradation color scale based on the conversion coefficients. Additionally, Nevo suggests that said functional image forming part determines the gradation color scale allocated to said functional image depending upon the pixel values of the pixels of the image data for each of RGB and upon various look-up tables (presepcifed colors, such as "high level – red," "mid level – yellow," and "low level – blue" to which the conversion coefficients are corresponded *(col. 5, line 54 – col. 6, line 10).*

Regarding Claim 10, Nevo discloses an apparatus according to claim 21, wherein said biological function data is at least one of the blood flow function data as represented by blood flow (*col. 8, line 16 – col. 9, line 25).*

Regarding Claim 22, Applicant should note that the fact that the biological function data being displayed is perfusion data of brain tissue does not *structurally* limit the display component of the present apparatus when the data is being displayed, and does not affect Nevo's

ability to display any particular type of data. Therefore, Nevo is capable of displaying biological function data such as perfusion data of brain tissue.

Response to Arguments

10. Applicant's arguments filed February 1. 2010, with respect to the rejection(s) of claim(s) 1 – 11, 13 – 19, 21, and 22 under Baba (WO 2004/024003) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Nevo (US 6,224,553 B1) as discussed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768